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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Paul J. Maddon, et al.

U.S. Serial No.:

09/891,119

Filed

June 25, 2001

For

Derivatives of Soluble T-4

1185 Avenue of the Americas New York, New York 10036

January 31, 2002

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

#### INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. § 1.56, applicants direct the Examiner's attention to the following references which are listed on PTO-1449 form attached hereto as **Exhibit 1**.

- 1. U.S. Patent No. 5,422,274, issued June 6, 1995, Maddon, et al;
- 2. U.S. Patent No. 5,126,433, issued June 30, 1992, Maddon, et al;
- 3. U.S. Patent No. 5,110,906, issued May 5, 1992, Maddon, et al;
- 4. U.S. Patent No. 4,520,113, issued May 28, 1995, Gallo et al:
- 5. U.S. Patent No. 4,629,783, issued December 16, 1986,

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Cosand;

- 6. U.S. Patent No. 4,663,436, issued May 5, 1987, Elder et al;
- 7. U.S. Patent No. 4,621; 054, issued November 4, 1986, Suzuki et al;
- 8. International Publication No. WO 88/01304, published February 25, 1998, DNA encoding the T cell surface protein T4 and use of fragments of T4 in the treatment of AIDS;
- 9. Blue, M., et al., (1985), Coexpression of T4 and T8 on peripheral blood T cells demonstrated by two-color fluorescence flow cytometry, <u>J. of Immunology</u>, 134:2281-2286;
- 10. Daldleisch, A.G., et al., (1984), The CD4 (T4) antigen s an essential component of the receptor for the AIDS retrovirus, Nature, 312:763-767;
- 11. Isobe, M., et al., (1986), The gene encoding the T-cell surface protein T4 is located on the human chromosome 12, Proc. Natl. Acad. Sci. USA, 83:4399-4402;
- 12. Klatzmann, D., et al., (1984), T-lymphocyte T4 molecule behaves as the receptor for human retroviruses LAV, Nature, 312:767-768;
- 13. Lasky, L.A., (1987), Delineation of a region of the human immunodeficiency virus type 1 gp120 glycoprotein critical for interaction with the CD4 receptor, Cell, 50:975-985;
- 14. Littman, D.R., et al., (1985), The isolation and structure

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of the genes encoding the human T cell molecules T4 and T8, Chemical Abstracts, 103:175, Column 1, abstract no, 190738;

- 15. Littman, D.R., et al., The Isolation and structure of the genes encoding the human T cell molecules T4 and T8, (1985)

  ICSU Short Rep, Vol. 2, (Adv. Gene Tech.), pp. 233-234;
- 16. Maddon, P.J., et al., (1985), The isolation and nucleotide sequence of a cDNA encoding the T cell surface protein T4: A new member of the immunoglobulin gene family, <u>Cell</u>, 42:93-104;
- 17. Maddon, P.J., et al. (1986), The T4 gene encodes the AIDS virus receptor and is expressed in the immune system and the brain, Cell, 47: 333-348;
- 18. McDougal, J.S., et al., (1986), Binding the human retrovirus HTLV-III/LAV/ARV/HIV to the CD4 (T4) molecule: conformation dependence, epitome mapping, antibody inhibition, and potential for idiotypic mimicry, J. of Immunology, 137:2937-2944;
- 19. McDougal, J.S., et al., (1986), Binding of HTLV-III/LAV to T4+ cells by a complex of the 110k viral protein and the T4 molecule, Science, 231:382-385;
- 20. Ratner, L., et al., (1985), Complete Nucleotide Sequence of the AIDS virus, HTLV-III, Nature, 313:277-284;
- 21. Terhorst, C.m, et al., (1980), Biochemical analysis of Human T-lymphocyte differentiation antigens T4 and T5, Science, 209:520-521;

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- 22. Wong-Staal, F., et al., (1984), Human T-lymphotropic retroviruses, Nature, 317:395-403;
- 23. Fisher. R.A., (1988), HIV infection is blocked in vitro by recombinant soluble CD4, <u>Nature</u>, 331:76-78; (Exhibit 5)
- 24. Hussey, et al., (1988), A soluble CD4 protein selectively inhibits HIV replication and syncyitium formation, <u>Nature</u>, 331: 78-81; (Exhibit 6)
- 25. Traunecker, A., (1988), Soluble CD4 molecules neutralize human immunodeficiency virus type 1, Nature, 331: 84-86; (Exhibit 7)
- 26. Deen, et al., (1988), A soluble form of CD4 (T4) protein inhibits AIDS virus infection, Nature, 331: 82-84; (Exhibit 8);
- 27. Capon, D.J., (1989), Designing CD4 immunoadhesins for AIDS therapy, Nature, 337: 525-531; and (Exhibit 9)
- 28. Dalgleish, A.G., et al, (1987), Neutralisation of HIV Isolates by Anti-Idiotypic Antibodies which Mimic the T4 (CD4) Epitope: A Potential AIDS Vaccine, <u>Lancet</u>, <u>2(8567)</u>: 1047-1050 (Exhibit 10).

The subject application is a continuation of U.S. Serial No. 08/328,500, filed October 25, 1994. The above listed references 4-22 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed on October 25, 1994, in connection with 08/328,500. The above-listed references 10, 12-13, 15-16, and 21 were cited in a search

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report in connection with PCT/US89/00762, a foreign counterpart of the subject application. Copy of the search report is attached hereto as **Exhibit 2**. The above-listed references 9-11, 16, and 19 were cited in a search report in connection with PCT/US87/02050, a foreign counterpart of the subject application. Copy of the search report is attached hereto as Exhibit 3. Accordingly, under 37 C.F.R. \$1.98(d) copies of these references are not required to be provided to the United States Patent and Trademark Office, since they were previously cited by, or submitted to, the United States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C §120. An European Search Report was also issued on November 10, 1990 in connection with EP 89 10 3297, a foreign counterpart of the subject application. A copy of this search report is attached hereto as Exhibit 4. The above listed references 23-28 were cited in that search report. Copies of references 23-28 are attached hereto as Exhibits 5-10.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone either of them at the number provided below.

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Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

1-31-02

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Exhibit 1

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

glycoprotein critical for interaction with the CD4 receptor, Cell, 50:975-985;

molecules T4 and T8, Chemical Abstracts, 103:175, Column 1, abstract no, 190738;

Littman, D.R., et al., The Isolation and structure of the genes encoding the human T cell molecules T4 and T8, (1985) ICSU Short Rep. Vol. 2, (Adv. Gene Tech.), pp. 233-234;

surface protein T4: A new member of the immunoglobulin gene family, Cell, 42:93-104;

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#### Form **PTO-1449**

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Serial No. 09/891,119

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Applicant

Paul J. Maddon, et al

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### BY APPLICANT (Use several sheets if necessary)

INFORMATION DISCLOSURE CITATION

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

McDougal, J.S., et al., (1986), Binding the human retrovirus HTLV-III/LAV/ARV/HIV to the CD4 (T4) molecule: conformation dependence, epitome mapping, antibody inhibition, and potential for idiotypic mimicry, J. of Immunology, pp. 2937-2944;

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